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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,377	03/16/2001	Matthew M. Graf	PA-5239-RFB	8787

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INDIANAPOLIS OFFICE 27879
BRINKS HOFER GILSON & LIONE
ONE INDIANA SQUARE, SUITE 1600
INDIANAPOLIS, IN 46204-2033

EXAMINER

HOOK, JAMES F

ART UNIT	PAPER NUMBER
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3754

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,377	GRAF ET AL.	
	Examiner	Art Unit	
	James F. Hook	3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,13,14 and 17-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,13,14 and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 13, and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys. The patent to Parker discloses the recited sheath comprising a shaft 16 extending from a proximal end portion to a distal end portion, a distal tip 12 at the distal end of the shaft, the distal tip section comprising polymeric material 34 containing 35-65% of a radiopaque material such as tungsten, where the shaft is less radiopaque than the distal tip section, the polymeric material can be polyamide, and the tip member was originally a separate member. The patent to Parker discloses all of the recited structure with the exception of using fluorinated ethylene propylene as the polymeric material. The patent to Coneys discloses that it is known in the art that fluorinated ethylene propylene can be used as sleeves in catheters when used in combination with radiopaque materials of varying amounts. It would have been obvious to one skilled in the art to modify the polymeric material in Parker to be made of any suitable plastic for use with catheters including fluorinated ethylene propylene as suggested by Coneys as such is a known equivalent plastic that is used with catheters provided with varying amounts of radiopaque materials as such is a material having more lubricious properties which would allow for easier insertion.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys and Hopkins. The patent to Parker discloses all of the recited structure with the exception of stating the size of the tungsten particles used and using FEP for the catheter. The patent to Hopkins discloses the recited use of radiopaque materials such as tungsten in a catheter, where it is known that the particles can be as small as 0.9 microns, which suggests they can be any size larger than 0.9 microns also. It would have been obvious to one skilled in the art to modify the tungsten in Parker to be of a size at least as small as 0.9 microns and larger as such are known particle sizes of tungsten used in radiopaque catheters as suggested by Hopkins as such would be more easily visible. The patent to Coneys discloses that it is known in the art that fluorinated ethylene propylene can be used as sleeves in catheters. It would have been obvious to one skilled in the art to modify the polymeric material in Parker to be made of any suitable plastic for use with catheters including fluorinated ethylene propylene as suggested by Coneys as such is a known equivalent plastic that is used with catheters provided with varying amounts of radiopaque materials as such is a material having more lubricious properties which would allow for easier insertion.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, and 13 above, and further in view of Hopkins. The patent to Parker as modified discloses all of the recited structure with the exception of stating the size of the tungsten particles used. The patent to Hopkins discloses the recited use of radiopaque materials such as tungsten in a catheter, where

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it is known that the particles can be as small as 0.9 microns, which suggests they can be any size larger than 0.9 microns also. It would have been obvious to one skilled in the art to modify the tungsten in Parker as modified to be of a size at least as small as 0.9 microns and larger as such are known particle sizes of tungsten used in radiopaque catheters as suggested by Hopkins and such would be more easily visible.

Response to Arguments

Applicant's arguments filed July 23, 2004 have been fully considered but they are not persuasive. With respect to the argument that it was not known nor obvious to use FEP highly loaded with radiopaque materials as a distal tip is not persuasive for the following reasons: Coneys teaches high loadings of radiopaque materials in FEP so such teaches that it was known to that it could be done, secondly the material in Coneys extends to the end of the sheath which puts high loadings in FEP at the end, the patent to Parker teaches highly loading a tip with the sheath having lower loadings, and unless the allegations of the criticality of the limitations recited in the rejected claims are supported by actual proof, they cannot be given any weight in determination of the issue of obviousness. In re Eisenhut (CCPA 1957), 245 F.2d 481, 114 U.S.P.Q. 287. The subject matter as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made... since it has been held to be within the general skill of a worker in the art to select a material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 U.S.P.Q. 416. Moreover, a newly discovered property does not render a compound unobvious, if (1) the claimed compound is structurally obvious from a prior art compound, (2) the claimed

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compound possesses the same property for which the prior art compounds were useful, and (3) the prior art compound in fact possesses the newly discovered property of the claimed compound. Monsanto Co. v. Rohm & Haas Co. (DC ED Pa 1970) 420 F2d 950, 164 U.S.P.Q 556. The patent to Parker clearly teaches using highly loaded tip portions with lesser loaded shaft body loadings and making the two of the same material, and specifically the particular loadings required are also given. Coneys teaches that FEP can be used, including into the tip portion, and can be highly loaded and that one can expect success as set forth above. With respect to the addition of "consists essentially of" to new claim 17, such is only referring to the tip portion, and as set forth above, the highly loaded tip portion is taught by Parker and the use of FEP to form the tip and body portions is considered obvious as taught by Coneys where the only modification being made by Coneys is material, not structural, and Parker meets all the structural limitations with no other layers. Coneys teaches the equivalence of using FEP in place of other materials when making body and tip portions having loadings of radiopaque material. The arguments from the last office action are still pertinent in response to repeated arguments in the recent amendment, and are repeated below.⁴

With respect to reference to Coneys, it is being used to teach the use of an FEP material to make a medical tube, the fact that it also is loaded is used to merely set forth that the material is capable of being loaded, however, for all loading values, the base reference to Parker teaches the required ranges. Therefore, the use of FEP is what the reference to Coneys is in fact teaching. The further structure of Coneys is immaterial to whether it teaches that FEP can be used as an alternative plastic material

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in medical tubes which can be loaded to make them more radiopaque. The arguments set forth appear to suggest that Coneys in some way is teaching other additional structure other than a change of plastic material used as the base plastic for the tube. Additionally arguments seem to suggest that a more detailed claimed apparatus is being argued than the claims currently support, specifically there is no claim language limiting the structure of the tubular layer that suggests that the tip and the sleeve are formed of an integral one piece structure, therefore arguments that the references are more complicated is based more on the applicant's specification than the claimed apparatus limitations. Likewise the arguments about stents, and sizes of the apparatus relating to the use with stents, as well as complexity of structure for such use are all more detailed than the claim language which does not require use with stents or any other structure specific to stent use only. Also, there is no claim language that the tip is securely bonded to the main shaft body, only that it is thermal bonded which does not necessarily insure a secure bond, so such is a more detailed argument than the claim language supports. In light of the teachings of the references, and the fact that they are very closely related, and that Coneys teaches alternate material used in these similar medical tubes, as per MPEP 2144.06 a prima facie case can be supported by combining equivalents known for the same purpose where Coneys acknowledges that FEP can be used for the same type of medical tubing use as that taught in Parker, and that there are advantages to using FEP for its properties over prior materials. Therefore, it is not persuasive that the two references require hindsight reasoning to combine when they are both dealing with the same application and that the reference to

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Coneys teaches the advantages of using FEP as a known equivalent material used in forming radiopaque medical tubes. The fact that Coneys is teaching the use of FEP is not contrary to the teachings of Parker when Parker teaches the use of a different material, polyamide, to form the sheath and the end, where the end is loaded differently than the sheath, but rather is teaching that an alternate material to be used for the wall of a medical tube which is capable of being made radiopaque is available and that such a material has properties which are more useful than previous materials. With respect to the teachings of Hopkins, it should be noted that Hopkins is being used solely to describe the relative size of tungsten particles used in medical radiopaque tubes since the base reference to Parker is silent to the size of the particles of tungsten used. It is immaterial as to where or what structure is formed by the particles in Hopkins when such is being relied on solely to teach what sized particles are used in loaded plastic materials used as radiopaque material in a medical tube, and nothing more. It is immaterial what structure, other than the particle size, is taught by Hopkins, it is not being used as a substitution of the band of radiopaque material at the end, only as a suggestion of what sized particles can be used in the sleeve in Parker as is known in the art, and at the very most a substitution of one tungsten particle having no specific size requirement in Parker with one having a suggested size as set forth by Hopkins.

Further, in summation, with respect to Coneys being used to modify the plastic, the argument that it would some how fall apart is not suggested by Coneys and such is only being used to teach using a different plastic material, not substituting any cut pieces or structure from Coneys. Likewise, the combination does not create more

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structure but is merely using the teachings of Coneys to modify the type of plastic used in Parker, not any change in structure. The loading of Coneys is immaterial when it is being used solely to teach using a different type of plastic material, Parker discloses the required range of loading, and such an argument is more detailed than the claim language when the claims talk about amount by weight of radiopaque material and not "effective loading", if the layer has that loading it meets the claim language regardless of whether the effective result is different in use. The structure of Parker having modified plastic is not considered to be any more complex than applicants structure. With respect to Hopkins, this reference is only being used to teach what materials are known in the art to be used in markers to provide radiopaqueness to sheaths, it is not being used to teach any structure other than the type of material is being used to make something radiopaque.

It should be noted that Coneys is merely used to teach the substitution of one type of plastic material for another, all of the rest of the structure is set forth in the base reference. Therefore, Coneys need not teach any other structure other than the use of FEP for catheters, any arguments directed toward added structure shown in Coneys is moot when such is not relied on, only the use of the specific plastic is, where Coneys teaches that FEP can be loaded with radiopaque materials. It is also considered that even if Coneys was considered to require the outer layer such would not destroy the combination when applicant has not claimed the structure using the term consisting of, and the use of comprising allows the references to teach more structure than is required. With respect to the statement that Coneys teaches a different sheath

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structure such is not persuasive when Coneys is not the base reference relied upon to meet all of the applicant's claimed structure with the exception of using FEP to make the sheath of. Any argument directed toward Coneys structure is immaterial when such is merely used to teach the substitution of FEP for the sheath material used. With respect to Hopkins, a similar argument is made toward the teachings of much of the structure of Hopkins, however, Hopkins is only used to teach that radiopaque particles of a certain size are used in applications using radiopaque markers, and not to teach any other structure of the sleeve. Therefore, any argument directed toward the structure of Hopkins being different is immaterial when the only modification being made to the base reference is that of teaching the size of the radiopaque material used in an sheath for detection, the examiner is not replacing the tip of the base reference with the marker of Hopkins but merely teaching that in radiopaque sleeves a certain size of particle may be used.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Querns disclosing state of the art catheters with radiopaqueness.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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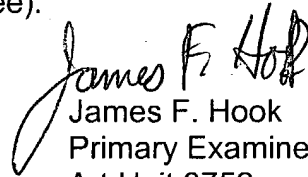
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James F. Hook whose telephone number is (703) 308-2913 until mid November at which point it will change to (571) 272-4903, and as of October 1, 2004 the examiner of record will be changing Art Unit designation number to 3754, therefore all further correspondence should be sent to the new Art Unit 3754, the examiner of record will remain the same. The examiner can normally be reached on Monday to Wednesday, work at home Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Mar can be reached on (703) 308-2087. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


James F. Hook
Primary Examiner
Art Unit 3752

JFH